GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON
RUTH L. KIRSCHSTEIN *NATIONAL RESEARCH SERVICE AWARD (NRSA)*
PREDOCTORAL FELLOWSHIP APPLICATIONS (F31)
SUPPORTED BY NINDS, NIAAA, NIBIB, NIDCD, NIDA, and NIMH

Note: The program announcement associated with this F31 award is PA-04-032. It can be found at http://grants.nih.gov/grants/guide/pa-files/PA-04-032.html *as well as on the CD-ROM*.

The goal of the Ruth L. Kirschstein National Research Service Awards for Predoctoral Fellows (F31) Program is to help ensure that highly trained, productive, and creative scientists will be available in adequate numbers and in appropriate research areas and fields to meet the Nation's health research needs. The goal of review is to identify those applicants who have the highest potential to develop into productive, independent scientists. Therefore, in preparing your comments, it is important to remember that the F31 program is a training award and not a research award. Major considerations in the review are the applicant's potential for a successful career and how the proposed training experience will help develop and realize that potential.

Each major element of the fellowship review (Applicant, Research Training Plan, Sponsor, and Institutional Environment/Commitment) should be commented on in a separate section of your written critique. **[Note that these criteria and section headings are different from those to be used when reviewing applications for Post-doctoral (F32) or other fellowships.]** For revised applications, also comment briefly on whether the application is improved, the same, or worse. Your review should consist primarily of evaluative statements, avoiding excessive descriptive material (e.g., listing every school attended and every job held by the candidate and/or the sponsor). After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit in a section titled Summary and Recommendation (see below).

Please note that your comments will be used essentially unedited in the final summary statement sent to the applicant.

REVIEW CRITERIA

APPLICANT: Assess the applicant's potential for and commitment to a productive scientific career. Since the goal is to identify applicants who have the highest potential to develop into productive independent scientists, this element of review is critical to the overall score. When evaluating the applicant's potential, you may consider the following items where relevant:

- The extent and level of previous education, including any undergraduate or graduate degree(s), the field, the date received or expected, academic performance, the mentor and the institution;
- Evidence of commitment to a career in research;
- Awards and honors, other relevant research experience, professional training, and publications;
- Reference letters, considering both the numerical rankings and the text of the letters (**Be sure to protect the confidentiality of the references**).

RESEARCH TRAINING PLAN: Briefly evaluate the merit of the research proposal and the general approach, considering the applicant's research background and the respective contributions of the applicant and the sponsor in the development of the research proposal. The proposal must have scientific merit, but unlike a research grant proposal, it should be evaluated in the light of the applicant's previous training and career development. Therefore, avoid a detailed critique of technical aspects of the research, but check for flaws so severe that they cast doubt on the applicant's or the sponsor's scientific judgment and qualifications or on whether such flawed research can serve as an appropriate vehicle for the candidate's development. The emphasis here should be on potential of the training plan to provide the fellow with individualized supervised experiences that will develop the candidate's knowledge and research skills, and not on the likely significance or impact on the field of the proposed research. If the research proposal involves human subjects, include an evaluation of the plan to include representation of both males and females, children (individuals under the age of 21), and members of minority groups as it relates to the scientific goals of the research. Also, evaluate the adequacy of plans to provide training in the responsible scientific conduct of research. Try to limit the written critique of the research training plan to a few paragraphs.

SPONSOR: Assess the qualifications of the sponsor, including evidence of his or her research expertise and success in competing for research support, understanding of and commitment to fulfilling the role of sponsor and mentor, understanding of the applicant's research training needs and ability to assist in meeting those needs, and prior experience as a mentor.

INSTITUTIONAL ENVIRONMENT/COMMITMENT: Evaluate the training environment, including the institutional commitment to research training and career development, the quality of the facilities and related resources (e.g., equipment, laboratory space, computers, subject populations), and the availability of research support.

SUMMARY AND RECOMMENDATION: Briefly summarize the strengths and weaknesses of the application and recommend an overall level of merit, weighting each of the review criteria as you feel appropriate. An application does not need to be strong in all categories to receive a good rating. Each scored application will receive a numerical rating that will reflect your opinion of its merit. The numerical rating is based on a scale from 1.0 for the most meritorious to 5.0 for the least meritorious with increments of 0.1 unit. Reviewers should score the "<u>average</u>" application they customarily review in their Scientific Review Group with a score of 3.0. This practice is designed to have 3.0 be the median.

Human Subjects: In applications with research proposals involving human subjects, consider the following:

Are Human Subjects involved? According to the new definition of human subjects, coded samples and data may not be considered human subjects use if they meet the criteria of:

a) the private information or specimens are not collected specifically for the proposed research through an interaction or intervention with living individuals,

b) the investigator cannot ascertain the identity of the individual to whom the coded private information or specimens pertain.

Exemptions Claimed: Express any comments or concerns about the appropriateness of the exemption(s) claimed. It should be noted that Exemption 4 is rarely used, as

applications that qualified for E-4 under the old guidelines (specimens or data sets) will qualify as no human subjects if they meet the two conditions cited above.

Protection of Human Subjects from Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Inclusion of Women Plan:
Inclusion of Minorities Plan:
Inclusion of Children Plan:
Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

Vertebrate Animals: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

***Note**:* Sections on Vertebrate Animals, Human Subjects and Biohazards are to be included only when applicable.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

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